§111.130 What quality control operations are required for returned dietary supplements?

Quality control operations for returned dietary supplements must include:

(a) Conducting any required material review and making any required disposition decision; including:

(1) Determining whether tests or examination are necessary to determine compliance with product specifications established in accordance with §111.70(e); and

(2) Reviewing the results of any tests or examinations that are conducted to determine compliance with product specifications established in accordance with §111.70(e);

(b) Approving or rejecting any salvage and redistribution of any returned dietary supplement;

(c) Approving or rejecting any re-processing of any returned dietary supplement; and

(d) Determining whether the reprocessed dietary supplement meets product specifications and either approving for release, or rejecting, any returned dietary supplement that is reprocessed.

§111.135 What quality control operations are required for product complaints?

Quality control operations for product complaints must include reviewing and approving decisions about whether to investigate a product complaint and reviewing and approving the findings and followup action of any investigation performed.

§111.140 Under this subpart F, what records must you make and keep?

(a) You must make and keep the records required under this subpart F in accordance with subpart P of this part.

(b) You must make and keep the following records:

1. Written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision and written procedures for approving or rejecting any reprocessing;

2. Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following:

(i) Date that the review, approval, or rejection was performed; and

(ii) Signature of the person performing the review, approval, or rejection; and

3. Documentation of any material review and disposition decision and followup. Such documentation must be included in the appropriate batch production record and must include:

(i) Identification of the specific deviation or the unanticipated occurrence;

(ii) Description of your investigation into the cause of the deviation from the specification or the unanticipated occurrence;

(iii) Evaluation of whether or not the deviation or unanticipated occurrence